## REMARKS

Claims 25, 27-38 and 40-47 are in the case and presented for reconsideration. Claims 39 and 48 have been canceled. Claims 25, 27, 28, 34, 35, 38, 39, 40, 42, 43, 44 and 45 have been amended. No new matter has been added.

Claims 25, 27, 28 and 30-48 have been rejected under 35 U.S.C. § 103(a) as being anticipated by U.S. Patent No. 6,575,969 (Rittman, III et al.) in view of the teaching of U.S. Patent No. 6,690,963 (Ben-Haim et al.). Claims 25, 27-40 and 42-48 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0109871 (Johnson et al.) in view of the teachings of Rittman, III et al. and Ben-Haim et al.

Applicant respectfully traverses as follows. The invention of Claim 25 as amended is directed to an apparatus for ablating cardiac tissue in the heart of a subject comprising a catheter which is adapted to be inserted into the body and within the heart so as to contact the cardiac tissue to be ablated at a desired position in the heart wherein the catheter comprises at least one position sensor which measures one or more local parameters at the position prior to after ablating the tissue and a position sensor which generates signals for determining position and orientation coordinates of the distal end of the catheter; an ablation device which applies a given dosage of energy to the tissue so as to ablate the tissue; a display which displays a map of the heart; and a controller which determines the position and orientation coordinates of the distal end of the catheter using the signals generated by the position sensor and which generates the map (based on the one or more local parameters measured by the at least one sensor) and determines a predicted extent of ablation of the tissue to be achieved for the given dosage of energy and an actual extent of the ablation determined subsequent to ablating the tissue for comparison with the predicted extent using the position and orientation coordinates.

Applicant's invention of Claim 40 is directed to an apparatus for ablating cardiac tissue in the heart of a subject comprising a catheter which is adapted to be inserted into the body and within the heart so as to contact cardiac tissue to be ablated wherein the catheter comprises a position sensor which generates an output indicative of a position and orientation of catheter

relative to the tissue with which the catheter is in contact; and an ablation device which applies a given dosage of energy to the tissue so as to ablate the tissue; a display which displays a map of the heart; and a controller which computes position and orientation coordinates of the distal end of the catheter based on the output from the position sensor and a prediction of an extent of ablation of the tissue to be achieved for the given dosage of energy so as to enable the dosage to be adjusted responsively to the prediction using the position and orientation coordinates of the catheter.

Rittman, III et al. discloses a cool-tip radiofrequency thermosurgery electrode system for tumor ablation. In some embodiments of the Rittman, III et al. reference, the probe uses a sensor that senses temperature (Column 7, Lines 9-15) or is used in conjunction with an ultrasonic scanner for ultrasonic imaging (Column 17, Lines 34-50). It is also important to note that Rittman III, et al. specifically teaches various electrode designs in order to reach specific target sites. See Abstract. Clearly, this is the solution for location of its various devices at a target site taught by Rittman, III et al. reference. Moreover, the Rittman, III et al. reference is not at all concerned with accurate location based on position and orientation coordinates of its various devices for use in comparing an actual extent of cardiac ablation to the predicted extent of ablation such as distinctly claimed by Applicant's claimed present invention. Rather, Rittman, III et al. achieves its location accuracy through use of different electrode device designs.

Ben-Haim et al. discloses a system for determining the location and orientation of an invasive medical instrument using a plurality of sensors. This reference is not in any way concerned with using the position and orientation coordinates of the catheter (based on the signals generated by the position sensor) for generating a map showing, based on the one or more local parameters measured by the at least one sensor, a predicted extent of ablation of the cardiac tissue to be achieved for a given dosage of energy, and an actual extent of the ablation determined subsequent to ablating the cardiac tissue, for comparison with the predicted extent using the position and orientation coordinates. Therefore, one skilled in the art would not be lead by the teaching of Rittman III, et al. to experiment with its cool-tip radiofrequency thermosurgery electrode system for tumor ablation. Thus, contrary to the Examiner's assertions, Ben-Haim et al. is actually evidence of the non-obvious of the present

invention. See *Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Additionally, there is nothing in Ben-Haim et al. that indicates that a skilled artisan would have been motivated, where using position and orientation coordinate information for comparison of the actual extent of ablation versus the predicted extent of ablation in a patient's heart was required, to provide an apparatus having a catheter with a position sensor which generates signals for determining position and orientation coordinates of the distal end of the catheter and a controller which uses the position and orientation coordinates of the distal end of the catheter (based on the signals generated by the position sensor) for generating a map showing, based on the one or more local parameters measured by the at least one sensor, a predicted extent of ablation of the cardiac tissue to be achieved for a given dosage of energy, and an actual extent of the ablation determined subsequent to ablating the cardiac tissue, for comparison with the predicted extent using the position and orientation coordinates. Ben-Haim et al. simply does not describe nor suggest this combination. It is clear that there is no incentive in Ben-Haim et al. to use its location system for generating a map showing, based on the one or more local parameters measured by the at least one sensor, a predicted extent of ablation of the tissue to be achieved for a given dosage of energy, and an actual extent of the ablation determined subsequent to ablating the tissue, for comparison with the predicted extent using the position and orientation coordinates such as found with Applicant's claimed present invention. Therefore, unless a Declaration under 37 C.F.R. § 1.107(b) is submitted by the Examiner to support this argument, it is not factually supported by the record and may not be the basis for a rejection under 35 U.S.C. § 103. See In re Wagner and Folkers, 152 U.S.P.Q. 552, 559 (CCPA 1967).

According to the Examiner's argument, the combination of Ben-Haim et al. with Rittman III, et al. in the rejection was directed toward providing motivation for modifying the structure of Rittman III, et al. or Ben-Haim et al. thereby providing a *prima facie* case of obviousness. However, neither Rittman III, et al. (nor Johnson et al. for that matter) in combination with Ben-Haim et al. render the present invention as claimed obvious.

The claimed present invention of Applicant's Claims 25 and 40 as amended does not use or claim the Rittman, III et al. reference's variations in electrode designs for achieving accurate location of a probe to a target site. And, Rittman, III et al. clearly teaches away from the position and orientation coordinate location technology for generating a map showing, based on the one or more local parameters measured by the at least one sensor, a predicted extent of ablation of the tissue to be achieved for a given dosage of energy, and an actual extent of the ablation determined subsequent to ablating the tissue, for comparison with the predicted extent using the position and orientation coordinates in which the Applicant is claiming. Thus at the time of Applicant's invention, the art actually taught away from the Applicants' invention. Thus, Rittman, III et al. taught away from the invention as claimed, and therefore, cannot rightly be combined with Ben-Haim et al. to render the present invention obvious.

Johnson et al. describes an apparatus for detecting and treating tumors using localized impedance measurement. As acknowledged by the Examiner, Johnson et al. fails to disclose a means to display a map of the predicted ablation of tissue for give applied dosage as well as a means to display the actual ablation in comparison to the predicted model. Moreover, Johnson et al. does not teach, suggest or even infer using a position sensor on the probe for generating signals indicative of the position and orientation coordinates of the probe and a controller which determines the position and orientation coordinates as found with the Applicant's claimed present invention as amended.

Thus, there is no suggestion or disclosure in Johnson et al., Ben-Haim et al., or Rittman, III et al. for making the claimed present invention of Applicant's invention. The only suggestion to combine position and orientation coordinate location technology for generating a map showing, based on the one or more local parameters measured by the at least one sensor, a predicted extent of ablation of the tissue to be achieved for a given dosage of energy, and an actual extent of the ablation determined subsequent to ablating the tissue, for comparison with the predicted extent using the position and orientation coordinates is provided by the Applicant's own Specification. Therefore, these prior art references are being improperly applied by the Examiner, using hindsight reconstruction to pick and choose elements from these references, in the face of contrary teachings in each of these references.

The PTO has the burden under section 103 of establishing a *prima facie* case of obviousness. This burden can only be satisfied by a legal conclusion based on underlying factual inquiries. See *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S., 82 USPQ2d 1389 (2007). Accordingly, it is clear that these references are of limited scope and content and provide teachings that are significantly different from Applicant's claimed present invention of independent Claims 25 and 40 and their dependent claims therefrom.

Additionally, neither Rittman, III et al., Ben-Haim et al., or Johnson et al., recognized or appreciated that the combination of an apparatus having a probe with at least one sensor for measuring one or more local parameters and a position sensor utilizing position and orientation coordinate location technology for generating a map showing, based on the one or more local parameters measured by the at least one sensor, a predicted extent of ablation of the tissue to be achieved for a given dosage of energy, and an actual extent of the ablation determined subsequent to ablating the tissue, for comparison with the predicted extent using the position and orientation coordinates as specified in Claims 25 and 40 of Applicant's claimed present invention. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established by the PTO. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 25 and 40 and the dependent claims depending either directly or indirectly therefrom.

Therefore, for the reasons outlined above, the Applicants claimed present invention is both patentably distinct and non-obvious over the cited prior art references, and favorable action is respectfully requested.

Respectfully submitted,

/Louis J. Capezzuto/
By: Louis J. Capezzuto
Reg. No. 37,107

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2218
Dated: July 9, 2007